

## REMARKS/ ARGUMENTS

Claims 18-58 are active in the present application. Although the Advisory Action did not indicate that the claim amendments filed July 11, 2003 were entered, Applicants presume that the amendments have been entered. If Applicants are incorrect, it is requested that the Amendments filed on July 11, 2003 be entered.

Applicants wish to thank the Examiner for withdrawing the rejection over Georges et al. The objections under 37 CFR 1.75(c) and the rejection under 35 U.S.C. § 112, second paragraph were addressed in the previous amendments submitted on July 11, 2003.

The remaining issue is the rejection under 35 U.S.C. § 112, first paragraph. This rejection is traversed for the reasons set forth previously and further in view of the following comments.

In short, it is the Office's opinion that the all of the claims are not enabled because of the alleged lack of description in the specification pertaining to how to make and use the invention coupled with the alleged unpredictability in the art evidenced by some publications cited by the Office. Applicants again respectfully disagree.

Rather than reiterate all of the comments already of record, Applicants would like to direct the Examiner's attention to the attached Declaration under 37 CFR 1.132 of Dr. Jerzy W. Kupiec-Weglinski. As stated in the Declaration and as evidenced by his attached curriculum vitae, Dr. Kupiec-Weglinski is unquestionably an expert in the transplantation field. Applicants will invite the Examiner to appreciate the breadth of Dr. Kupiec-Weglinski extensive experience and knowledge as well as his comments to the present invention. However, Applicants would like to particularly direct the Examiner's attention to a particular conclusion made by Dr. Kupiec-Weglinski. On page 2, paragraph 7, last sentence, Dr. Kupiec-Weglinski states:

**Thus, based on my knowledge of the field, I am convinced that *in vitro* IL-10 modified T cells will exert potent regulatory functions *in vivo*.**

Applicants also remind the Examiner of the other Declaration filed from Dr. Ritter, a named inventor of the application and also an expert in this field, who concluded (page 4, last paragraph):

**I conclude that the application as originally filed coupled with the knowledge readily available in the scientific field, demonstrates that one can make the claimed *in vitro* modified T-cells as claimed in this application as well as use those cells in transplantation protocols.**

Therefore, now Applicants have provided two Declarations from two experts in the field who conclude that the presently claimed invention is, in fact, enabled. The Examiner's reliance on general statements in various publications is not applicable here because those references have not reviewed the discovery of the present inventors nor assessed the pending claims. In contrast, both of the experts have specific knowledge of the invention (see paragraph 3 of the Dr. Kupiec-Weglinski) and conclude the same thing-THE INVENTION IS ENABLED. As a result the rejection under 35 U.S.C. § 112, first paragraph should be withdrawn.

In the event the Examiner's requires clarification on any issue in this case, she is invited to contact the Applicants' undersigned representative to resolve the matter expediently.

Applicants also request that this application be passed onto issuance.

Respectfully submitted,

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MAIER & NEUSTADT, P.C.

A handwritten signature in black ink, appearing to read 'Norman F. Oblon', with a long horizontal flourish extending to the right.

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